TexasMedical Association

PHYSICIANS CARING FOR TEXANS

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August 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: Docket No. 99N-1174

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's Center for Food Safety and Applied Nutrition to develop a strategy to achieve effective regulation of dietary supplements. The physician members of Texas Medical Association are concerned about the health and wellbeing of our patients and therefore support the Administrations attempts to balance consumer's access to dietary supplements while assuring the safety and proper labeling of these products.

The following comments are grouped according to the focus questions published in the June 18, 1999 Federal Register.

1. In addition to ensuring consumer access to safe dietary supplements that are truthful and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?

Comments: The FDA should continue to encourage and support research in the area of dietary supplements. The research should focus on assessing the safety of dietary supplement active ingredients, and the use of dietary supplements in the maintenance of health and/or prevention of disease. TMA supports the continued input from the Food Advisory Committee to provide FDA with scientifically founded recommendations concerning the safety of dietary supplement products. TMA also recommends that FDA continue to develop and enforce regulations that require dietary supplement manufacturers to ensure the efficacy of their products.

2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate? Which specific tasks should FDA undertake first?

Comments: Consumer safety and truth in labeling should be FDA's first priority for dietary supplements. The FDA should define acceptable manufacturing practices by

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which the industry can guarantee that a product's ingredients and amounts are truthful. FDA should also develop a standard set of definitions for (1) dietary supplements and (2) adverse events. For example, should there be differences in definition/classification of dietary supplements such as garlic and ginseng, and weight loss supplements with identifiable active ingredients like ephedrine.

In order to provide the public with "good information" on dietary supplements, the FDA must first have good data. TMA agrees that FDA should be the one to conduct follow-up investigations to substantiate any adverse events reported. This data collection and analysis requires proper funding so that accurate information can be disseminated.

TMA also supports increased education and accessibility to the MedWatch reporting system. Many physicians are not aware of the various reporting avenues, and are reluctant to report adverse events because of the length of time spent completing the form. The FDA may want to consider a two-step process for reporting. The first report could utilize a one-page report and include information such as the patient name, suspected name of substance, suspected adverse event, physician or name of individual making report. Additionally, the report could list the preferred method to contact the reporter in the event that additional information is needed. FDA analysts could review the case and assess the need for further information.

3. What factors should FDA consider in determining how best to implement a task?

Comments: TMA supports the use of regulations to improve labeling and safety requirements of dietary supplements. While guidance documents play an important role in explaining how industry and the agency may comply with those statutory and regulatory requirements. TMA supports FDA efforts to develop regulations and legally enforce those regulatory requirements.

4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

Comments: Finalize the June 1997 proposed regulations on ephedra. The public health risks associated with these products have not changed since promulgation of these rules and top priority should be placed on finalizing these regulations to address the risks.

5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure, for example, that consumers have confidence that the products on the market are safe, truthful, and not misleadingly labels?

Comments: If there is a known active ingredient in a dietary supplement, it should be listed as the pharmaceutical name along with the amount per dosage. Manufacturers should also be required to list possible drug interactions and safety concerns.

6. Toward what type or area of research on dietary supplements should FDA allocate its research resources?

Comments: The FDA should focus its research to issues of safety. Manufacturers should be responsible for conducting research to determine a product's efficacy

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy.

Comments: FDA should increase its surveillance through MedWatch and other current sources. FDA could prioritize based on selected hot topics or the current fad and research safety studies and provide meta-analysis of scientifically developed studies. Additionally, FDA should continue to work closely with state regulatory agencies and should increase education and outreach to health professionals about the role of MedWatch in identifying potentially unsafe products.

Thank you for the opportunity to provide comments into the Center's overall strategy to achieve effective regulations of dietary supplements.

Sincerely,

Robert H. Emmick, Jr, MD

Robert H. Emmick, Jr. MD
Vice Chair, Council on Public Health

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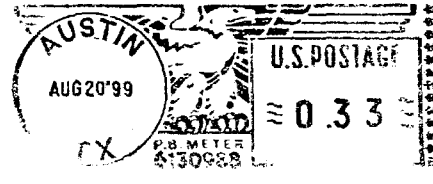

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